UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO: **THE WAVE ONE CASES IDENTIFIED IN EXHIBIT A TO ETHICON'S MOTION**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' RESPONSE IN OPPOSITION TO ETHICON'S MOTION TO EXCLUDE THE TESTIMONY OF ANNE WILSON

Plaintiffs submit the following memorandum of law in opposition to the "Motion to Exclude the Testimony of Anne Wilson" filed by Defendants Ethicon, Inc. and Johnson & Johnson (collectively "Ethicon"). Ms. Wilson's testimony should be admitted, in its entirety, for the following reasons:

INTRODUCTION

Anne Wilson ("Ms. Wilson") is a Biomedical Engineer and Quality Assurance Consultant with nearly thirty (30) years of professional experience focusing exclusively on risk management, design controls, and quality system development for medical devices. Her career has focused on medical device development, and she also consults with medical device companies, helping them develop and maintain safe and effective medical devices, including help with retooling quality systems and risk assessments, which are issues that lie at the very heart of this case. *See* Ex. A, Wilson TVT-R Report. Her reports not only explain the industry standards in this regard, but also and how Ethicon's design of its devices to treat Stress Urinary Incontinence ("SUI") failed to meet those standards.

Ethicon's Motion argues that Ms. Wilson's opinions are unreliable and, in some instances, incorrect. But in making these arguments, Ethicon ignores the evidentiary standards of Federal Rule 702 and *Daubert* and the well-established principles of design control and risk assessment for medical devices.

Ms. Wilson bases her opinions on well-accepted principles of medical device design control and risk assessment, the documents produced in this litigation, as well as nearly thirty (30) years of experience in device design and risk assessment for medical devices. *See* Ex. A, Wilson TVT-R Report at 1-3. And because Ms. Wilson's testimony is based on a sound methodology and will assist the jury's understanding of these issues, it should be allowed at trial. Ethicon's Motion to Exclude Ms. Wilson's Testimony should be denied.

STANDARD OF LAW

Under Rule 702 of the Federal Rules of Evidence, expert testimony must satisfy a two-prong test: (1) the testimony must concern "scientific, technical, or other specialized knowledge," and (2) it must aid the jury to understand or resolve a fact at issue. *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 260 (4th Cir. 1999), *citing Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 593 (1993); Fed. R. Evid. 702. The first prong is aimed at excluding so-called "junk science." *Daubert*, 509 U.S. at 593. Courts should examine whether the reasoning or methodology underlying the expert's preferred opinions is reliable. *Westberry*, 178 F.3d at 257; *Daubert*, 509 U.S. at 593. The second prong relates to the testimony's relevance. Relevancy is satisfied where the expert's opinion is one that will be helpful to the trier of fact. *Daubert*, 509 U.S. at 591.

The *Daubert* Court listed specific factors to guide the overall relevance and reliability determinations that apply to all expert evidence. They include (1) whether the particular

scientific theory can be (and has been) tested"; (2) whether the theory "has been subjected to peer review and publication"; (3) the "known or potential rate of error"; (4) the "existence and maintenance of standards controlling the technique's operation"; and (5) whether the technique has achieved "general acceptance" in the relevant scientific or expert community." *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003), *quoting Daubert*, 509 U.S. at 593–94. However, "[t]he inquiry to be undertaken by the district court is a flexible one." *Westberry*, 178 F.3d at 261, *Daubert*, 509 U.S. at 594–95; *Kuhmo Tire*, 526 U.S. at 141. In the end, an expert's testimony is admissible under Rule 702 if it "rests on a reliable foundation and is relevant." *Kuhmo Tire*, 526 U.S. at 141.

The court's focus in a *Daubert* inquiry should be solely on experts' "principles and methodology, not on the conclusions they generate." *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). Notably, "the Supreme Court itself viewed *Daubert* as a *liberalization*, not a tightening, of the rules controlling admission of expert testimony." *Cavallo v. Star Enterprise*, 100 F3d 1150, 1158 (4th Cir. 1996) (emphasis added). Further, "exclusion is the least favored means of rendering questionable scientific evidence ineffective." *Id*. Weaknesses in the underpinnings of the expert's opinion go to the opinion's weight, rather than its admissibility. *Pugh v. Louisville Ladder, Inc.*, 361 Fed. Appx. 448, 456 (4th Cir. 2010). Rejection of expert testimony is to be the "exception rather than the rule." *United States v. Stanley*, 533 Fed. Appx. 325, 327 (4th Cir. 2013). The proponent need not prove that the expert's testimony is correct, as the validity of the expert's conclusions is for the finder of fact to determine. *Westberry*, 178 F.3d at 261. Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the "traditional and appropriate" means of attacking expert testimony. *Daubert*, 509 U.S. at 596; *Cavallo*, 100 F.3d at 1158.

ARGUMENT

All of Ms. Wilson's opinions are relevant to the ultimate question of liability that the jury will decide in this case and her opinions are reliably based in the scientific method and relevant industry standards. Furthermore, Ms. Wilson's opinions are supported by the internal statements and conclusions of Ethicon researchers who have looked at the design of Ethicon's SUI devices and the defects inherent to them.

A. Ms. Wilson's opinions are reliable because they are based on a sound methodology applied to the facts of the case

Ethicon's assertion that Ms. Wilson's opinions are unreliable because they are not based on a formal audit is without merit. Def's Memo at 2-4. As this Court has previously noted, "[t]he Supreme Court has said that '[t]he objective of] the *Daubert* gatekeeping] requirement…is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.'" *Mathison v. Boston Sci. Corp.*, No. 2:13-cv-05851, 2015 U.S. Dist. LEXIS 59047, at *33 (S.D. W. Va. May 6, 2015) (*quoting Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (U.S. 1999). Ms. Wilson looks at a medical device manufacturer's risk management processes and identifies its strengths and weaknesses every day in her profession. Ex. B, Wilson Dep. 9/17/2015 at 417:23–419:4.

As Ms. Wilson testified, she utilized the same methodology in preparing this case as she does in her everyday work:

> Q. So just to be clear, you have actually walked in the doors of medical device companies over the course of your career and performed the same analyses that you performed here, right, by looking at their risk management processes and identifying strengths and/or weaknesses?
> A. Right. Those would be called -- like we call them gap analyses. They're not audits. So we would go in and do a gap analysis to look, gee, how did they, you

> know, comply with the standards? How did they respond over time? How do their documents, you know, look? And then we provide them a management report.
>
> Q. And when you did your expert report in this case, did you use the same methodologies that you use in your professional consulting for medical?
>
> A. Yeah. It's similar. And then I look—I consider my background and experience. I looked at—as an auditor, I looked at my consulting. And then I use all of those skills together to come up with a report, looking at the gaps and the opportunities for improvements.

Ex. B, Wilson Dep. 9/17/2015 at 417:23–419:4.

Moreover, Ms. Wilson explained at the outset of her expert reports that her methodology in this case is the same methodology she applies in her profession:

> In my profession as a Biomedical Engineer and Quality Assurance Consultant for medical device companies, I routinely analyze medical device manufacturers' risk management processes and identify their strengths and weaknesses. I regularly look at medical device companies' design and risk management documents, including design history files and FMEAs, and evaluate whether that documentation complies with industry standards and practices. For example, I routinely use root cause analysis methodologies to identify the deficiencies in medical device companies' processes such as design control, risk management, production issues, or CAPAs. These are the same analysis methods that I have performed in the course of my work in this case.

Ex. A, Wilson TVT-R Report, at 3; Ex. C, Wilson TVT-O Report, at 3; Ex. D, Wilson TVT-S Report, at 2-3. Her expert reports provide the framework for her analysis and opinions in this case by listing and explaining the "Relevant International Standards Covering Quality Management Systems" for medical devices, as well as the accepted procedures for risk management within the medical device industry. *See* Ex. A, Wilson TVT-R Report at 4–11. Ms. Wilson's framework for her analysis in this case is her experience in the industry, generally accepted practices, and current standards. Ex. B, Wilson Dep. 9/17/2015 at 45:20–46:8. As Ms. Wilson explained in her reports, the methodology she utilized in arriving at her opinions was to review Ethicon design and risk documents within the framework of industry standards, and to

evaluate whether Ethicon's design and risk management of the TVT device complied with those industry standards. *See* Ex. A, Wilson TVT-R Report at 13-14. There is nothing unreliable about her methodology, and her opinions should not be excluded.

B. Whether European authorities found that Ethicon complies with certain industry standards goes to the weight of the testimony, not the admissibility of that testimony

Ethicon's contention that European authorities found that the TVT device complied with industry standards when it was first sold is not a proper basis for limiting or excluding Ms. Wilson's opinions in this case. *See* Def's Memo at 4. This is a contested issue with which Ms. Wilson disagrees. She has explained that, in her professional experience, whether or not a manufacturer has complied with certain industry standards cannot be based solely on certificates which state that a particular standard may have been met. *See* Ex. B, Wilson Dep. 9/17/2015 at 115:16–116:6; 398:19–399:23; *see also* Ex. A, Wilson TVT-R Report at 14. Furthermore, Ms. Wilson was able to explain why an audit, which only captures a "specific snapshot in time," is not relevant to whether a manufacturer has complied with industry standards. Ex. B, Wilson Dep. 9/17/2015. at 39:7–20.

Moreover, Ethicon's arguments conflict with the prior rulings of this Court. As this Court has found, it "need not determine that the proffered expert testimony is irrefutable or certainly correct"—"[a]s with all other admissible evidence, expert testimony is subject to testing by 'vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" *Edwards v. Ethicon, Inc.*, No. 2:12-cv-09972 2014 U.S. Dist. LEXIS 92316, at *4 (S.D. W. Va. July 8, 2014); *see also Pugh*, 361 Fed. Appx. at 456 (Any weaknesses in the underpinnings of an expert's opinion go to the opinion's weight, rather than its admissibility). As this Court noted in *Mathison*, a defendant may properly "cross-examine and impeach [an

expert witness] at trial regarding any perceived oversights in her analysis." *Mathison*, 2015 U.S. Dist. LEXIS 59047, at *55.

At its heart, this argument is nothing more than conflicting expert opinions. But as this Court has previously found, '[m]ere disagreement among experts is not, in itself, a reason to exclude an expert's testimony." *Edwards*, 2014 U.S. Dist. LEXIS 92316, at *70 (*citing Daubert*, 509 U.S. at 580) (stating that the court's "focus must be solely on principles and methodology [the experts use], not on the conclusions that they generate")). Moreover, one of Ethicon's expert's in this case, Elaine Duncan, admitted at her deposition that it is possible for different people who have expertise in risk management to review the same materials and come to different conclusions. Ex. E, Elaine Duncan Deposition, 10/6/2015 at 145:23–146:8. For each of these reasons, Ethicon's *Daubert* challenge must be denied.

C. Ms. Wilson's opinions are not based on European regulatory standards

Ethicon is also incorrect when it represents that Ms. Wilson's opinions are based on European regulatory standards. *See* Def's Memo at 5-11. At her deposition in the *Mullins* case, Ms. Wilson was explicit that her opinions were not based on *any* regulatory standards. Ex. B, Wilson Dep. 9/17/2015 at 49:16–22 (Q. "Were any of the materials that you considered in forming this report, materials that would also be part of regulatory submissions in relation to these products? A. I did not look at any regulatory submission documents."). Instead, Ms. Wilson's opinions discuss standards set by the International Organization for Standardization (ISO), including ISO 13485 and ISO 14971, which are industry standards relating to Quality Systems and Risk Management requirements for medical devices. *See* Ex. A, Wilson TVT-R Report at 4–6; Ex. C, Wilson TVT-O Report at 4-6; Ex. D, Wilson TVT-S Report at 4-5. These standards define the requirements for proper risk analysis in the medical device industry. *Id.*

This Court has previously allowed expert witnesses to testify regarding how standards set by the ISO apply to implantable medical devices, and part of Ms. Wilson's expertise lies in the same vein. *See Mathison*, 2015 U.S. Dist. LEXIS 59047, at *98 (allowing Dr. Spiegelberg, a witness for Boston Scientific, to opine on ISO standards based on his "extensive experience in the field of medical device analysis and design."). In accordance with this Court's prior rulings, "identifiable industry standards," such as ISO standards may provide a "reliable, objective basis for [expert] testimony." *See id.* at *33 (quoting *Lasorsa v. Showboat: The Mardi Gras Casino*, No. 07-4321 2009 U.S. Dist. LEXIS 81948, at *13 (D.N.J. Sept. 9, 2009)).

Additionally, in *Cisson*, this Court allowed the defendant to present evidence regarding its compliance with ISO standards. *Cisson v. C.R. Bard, Inc.*, No. 2:11-cv-00195 2013 U.S. Dist. LEXIS 149976, at *36 (S.D. W.V. Oct. 18, 2013) ("Similarly, evidence that Bard complied with standards set by the International Standards Organization (ISO) would not preclude the jury from awarding punitive damages. This evidence shows that Bard conducted biocompatibility and risk analysis in accordance with ISO standards."). Here, like in *Cisson*, evidence regarding whether or not a manufacturer's complied with ISO standards is relevant and admissible.

Ethicon's argument that Ms. Wilson's mention of MIL-Q-9858A is irrelevant does not accurately reflect the substance of Ms. Wilson's reports. Def's' Memo at 6. Ms. Wilson mentions this standard as a historical example of an early QMS—she does not represent that it is directly applicable to modern medical device manufacturers. *See* Ex. A, Wilson TVT-R Report at 4. Ethicon also suggests that ISO 9001 and EN 46001 are irrelevant. Def's Memo at 4. But Ms. Wilson clearly explains the relevance of these standards in her reports. *See* Ex. A, Wilson TVT-R Report at 5 (noting that these standards include requirements to "identify requirements that are related to the safety of the medical device…").

Ethicon's assertion that certain standards which Ms. Wilson relies upon must be retroactive to apply to these cases is similarly unfounded. Ms. Wilson explained in her reports that many of the standards she cites existed before the TVT-R device was first marketed in the United States. *See* Ex. A, Wilson TVT-R Report at 5 (noting that "ISO 13485 has defined the requirements for proper risk analysis in the medical device industry since 1996."). Moreover, standards that were not adopted until after the TVT was first marketed in the United States are also relevant because they define how a manufacturer must update the design and risk assessment of a device by taking into account customer feedback of that device. *See* Ex. A, Wilson TVT-R Report at 5 (noting that ISO 13485 defines how to "handle complaints and product or system related CAPAs [corrective action and preventative actions] once a manufacturer becomes aware of feedback from any source."). Ethicon's contention that certain standards must be retroactively applied solely focuses on the TVT-R device, and completely ignores Ethicon's TVT-O and TVT-S devices, which were not designed and marketed in the U.S. until after the dates when Ethicon concedes these standards were adopted. *See* Def's Memo at 6-9.

Ms. Wilson does not intend to retroactively apply standards; she is simply explaining how Ethicon's conduct in the original design and continued risk assessment of the TVT device measures against standards and industry practices existing at the time of that conduct. Moreover, Ms. Wilson's opinions in this case are not based solely on industry standards. Ms. Wilson's opinions in this case are built upon her professional knowledge and extensive risk assessment experience in the medical device industry. *See* Ex. A, Wilson TVT-R Report at 1-3.

Ethicon's assertion that the industry standards upon which Ms. Wilson relies are irrelevant because they have not been adopted by the FDA is without merit. *See* Def's Memo at

6. Ms. Wilson intentionally excluded any consideration of, or reference to, the FDA in her reports. Ex. B, Wilson Dep. 9/17/2015, at 181:9-14 ("I'm going to go back. My report, I exclusively -- I did not look at FDA because that was outside of the scope of my report. So I just want to make sure that you're aware of that."); *id.* at 393:22-394:22; Ex. F, Wilson Dep. 3/22/2016 at 31:17-23. Moreover, in *Mathison*, this Court rejected the suggestion that "the binding effect of industry standards dictates their reliability." *Mathison*, 2015 U.S. Dist. LEXIS 59047, at *43-44. As this Court recognized in *Cisson*, "evidence of [a manufacturer's] compliance with ISO standards is relevant." *Cisson*, 2013 U.S. Dist. LEXIS 149976, at *36. Here, like in *Cisson*, evidence of whether or not a manufacturer has complied with ISO standards is relevant to Plaintiffs' claims.

Finally, Ethicon's assertion that the industry standards upon which Ms. Wilson relies would cause unfair prejudice is without merit. *See* Def's Memo at 9-11. Ethicon attempts to equate ISO standards with FDA regulations and asserts that like FDA regulations, ISO standards could confuse and mislead the jury. *Id*. In *Mathison*, this Court considered and rejected a similar *Daubert* challenge to opinions of Plaintiff's expert witness, Dr. Peggy Pence:

> This argument misunderstands my concern with introducing FDA evidence. If I allowed BSC to express to the jury that its product complied with FDA regulations, the jury would then view the product with the gloss of federal-government endorsement, given that the product was cleared for market through the FDA's 510(k) process, which 'does not in any way denote official approval of the device.' 21 C.F.R. §807.97 (2012). GHTF standards, on the other hand, do not carry the same prejudicial force—the government does not promulgate them, manufacturers are not bound by them, and jurors are not familiar with them. And although the FDA appears to have had a limited role in the activities of GHTF, [] that role was not instrumental or definitive, and the work of the GHTF can be described without reference to the FDA. Accordingly, I find BSC's argument without merit.

Mathison, 2015 U.S. Dist. LEXIS 59047, at *43-46 (internal citations omitted). Here, like in *Mathison*, Ms. Wilson's reliance upon industry standards does not run afoul of this Court's prior

FDA rulings. Ms. Wilson's opinions in this case do not concern the FDA, but instead are focused on whether Ethicon's design of the TVT-R, TVT-O, and TVT-S meet identifiable industry standards. *See* Ex. A, Wilson TVT-R Report at 2-4. Ms. Wilson has testified that she can offer these opinions at trial without reference to the FDA. *See* Ex. B, Wilson Dep. 9/17/2015 at 393:22-394:22. This Court has previously allowed Dr. Spiegelberg to testify regarding medical device design and risk assessment based on ISO standards, as long as he did not mention in the FDA. *Mathison*, 2015 U.S. Dist. LEXIS 59047, at *98 ("[T]o the extent Dr. Spiegelberg intends to opine on ISO standards without referencing the FDA, I find him qualified to do so.").

D. Ms. Wilson's opinions have a reliable foundation in Ethicon's own documents

Ethicon's assertion that Ms. Wilson's opinions should be excluded because she did not review certain documents is incorrect. Def's Memo at 11-18. Ms. Wilson's reports and deposition testimony confirm that she has reviewed thousands of pages of Ethicon documents in forming her opinions in this case. *See* Ex. B, Wilson Dep. 9/17/2015 318:13–24; 379:15–24; *see* Ex. A, Wilson TVT-R Report; Ex. C Wilson TVT-O Report; Ex. D, Wilson TVT-S Report. In her reports, Ms. Wilson explains that she "analyzed, reviewed, and relied upon" "Ethicon documents, including, but not limited to risk management documents, and quality assurance documents," as well as "[d]eposition transcripts of Ethicon employees." Ex. A, Wilson TVT-R Report at 2. Ms. Wilson further explained that she reviewed the entire design history files for the TVT-R, TVT-O, and TVT-S devices in connection with the design process and risks that were considered by Ethicon in the design of these devices. Ex. A, Wilson TVT-R Report at 15; Ex. C, TVT-O Report at 11; Ex. D, TVT-S Report at 12.

Whether Ms. Wilson's review of Ethicon documents included every document that Ethicon deems relevant is an issue that goes to weight of testimony and not the admissibility of

that testimony, and is, therefore, a subject for cross-examination and impeachment. Indeed, as this Court has previously noted: "[a]n expert's failure to examine a particular source of information is not grounds for exclusion under *Daubert*, so long as the expert has other 'sufficient facts or data' to support her opinion. *Mathison*, 2015 U.S. Dist. LEXIS 59047, at *55 (*citing* Fed. R. Evid. 702). That is because, a defendant may properly "cross-examine and impeach [an expert witness] at trial regarding any perceived oversights in her analysis." *Id.*

Additionally, Ms. Wilson's opinions do not rest solely upon her review of Ethicon documents. Ms. Wilson's opinions are also reliable because they are based on her knowledge, skill, experience, training, and education as a biomedical engineer and quality assurance consultant. *See* Fed. R. Evid. 702 (noting that a witness may be "qualified as an expert by knowledge, skill, experience, training, or education."). Ms. Wilson's opinions in this case are built on her knowledge of the medical device industry and her nearly thirty (30) years of experience as a Biomedical Engineer in quality assurance. *See* Ex. A, Wilson TVT-R Report at. 2. Ms. Wilson holds certifications as a Certified Quality Auditor, Certified Quality Engineer, and Certified Quality Manager through the American Society for Quality, a Quality System Lead Auditor through Exemplar Global, and as a Registered Quality Assurance Professional in Good Laboratory Practice through the Society of Quality Assurance. *See* Ex. A, Wilson TVT-R Report at 1. Ms. Wilson's work experience includes extensive experience with permanently implantable medical devices, including heart valves, artificial joints, shoulder anchors, cervical plates, and medical screws. Ex. B, Wilson Dep. 9/17/2015, at 388:16–391:5. She founded and presides over a company that "consults with medical device manufacturers to develop and implement compliant solutions for their quality practices. Ex. A, Wilson TVT-R Report at 1. Ms. Wilson's background and credentials more than qualify her to testify regarding medical

device industry risk assessment and quality standards and whether Ethicon's design of the TVT device complied with those practices and standards.

As the Fourth Circuit has recognized, the adequacy of an expert's knowledge goes to the weight of the testimony, not its admissibility, and thus presents a jury question. See *Humphries v. Mack Trucks, Inc.*, No. 98-1970, 1999 U.S. App. LEXIS 25522, at *14 (4th Cir. Oct. 13, 1999). Moreover, courts have recognized that "an expert may base his opinion on experience alone…" *Figueroa v. Boston Sci. Corp.*, 254 F. Supp. 2d 361, 368 (S.D.N.Y. 2003) ("[T]he fact that an expert 'may have neglected to perform some 'essential' tests or measurements…goes to the weight of his testimony, not its admissibility") (*quoting Lappe v. Am. Honda Motor Co.*, 857 F. Supp. 222, 228 (N.D.N.Y. 1994). For these reasons, Ethicon's motion must be denied.

E. Ms. Wilson does not misapply the industry standards she relies upon

Next, Ethicon wrongly asserts that Ms. Wilson's opinions should be excluded because she "misapplied" industry standards and that her opinions are unreliable and, in some instances, incorrect. Def's Memo at 19-24. That is simply not so.

Ethicon asserts that Ms. Wilson misapplies ISO 14971 because she takes the position that any risk is unacceptable and that her definition of safety is different than the definition contained in ISO 14971. Def's Memo at 19. But Ethicon mischaracterizes Ms. Wilson's opinions. In her reports, Ms. Wilson clearly explains that the ISO 14971 framework for risk is that: "[i]t is accepted that the concept of risk has two components: a) the probability occurrence of harm; [and] 2) the consequences of that harm, that is how severe it might be." Ex. A, Wilson TVT-R Report at 6. Ms. Wilson further explains that this concept of risk is one of the "basic concepts of patient safety." *Id*.

Ethicon's argument that Ms. Wilson's opinions failed to take into account whether or not a medical device was "state of the art" is also without merit. Def's Memo at 19-20. The weighing of contrary evidence regarding the safety and design of Ethicon's SUI devices is for the finder of fact to determine. *See Daubert*, 509 U.S. at 596 ("vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking expert testimony.").

Likewise, Ethicon's argument that Ms. Wilson seeks to retroactively apply standards to Medscand's design documentation is unfounded. Def's Memo at 20. Ms. Wilson does not intend to retroactively apply standards; she is simply explaining how Ethicon's conduct in the design and continued risk assessment of Ethicon's SUI devices measures against standards and industry practices existing at the time of that conduct. For example, Ms. Wilson testified in *Mullins* that she has reviewed an audit of Medscand by Ethicon which highlighted non-conformances with design documentation requirements. Ex. B, Wilson Dep. 9/17/2015 at 64:4-18. Ms. Wilson seeks to explain how non-conformances such as this are important to a manufacturer's risk assessment

Ms. Wilson explains in her reports that missing documentation relating to the design of the TVT-R device is a violation of medical device industry practices. See Ex. A, Wilson TVT-R Report at 15. Defendant cavalierly asserts that Ms. Wilson's criticism in this regard is unsupported because, "for obvious reasons," Ethicon would not have these documents for a device they purchased for a different manufacturer—but Ethicon offers no support for its position that such documentation was not available to it. Def's Memo at 21.

Ethicon also takes issue with Ms. Wilson's discussion of its "design history file remediation." Def's Memo at 15. Here, Ethicon accuses Ms. Wilson of deliberately misquoting

a document "in order to create a false impression" and "deceitfully" using this document. *Id*. Ms. Wilson's mention of this document serves only to provide historical information regarding when Ethicon took over the design control activities from Medscand. Ex. A, Wilson TVT-R Report at 15. Ms. Wilson discussed the significance of Ethicon taking over the design control of the TVT-R product from Medscand at her deposition. Ex. B, Wilson Dep. 3/22/2016 at 111:10-24.[1] Moreover, if Ms. Wilson is wrong about what the document says, that is an issue for cross examination.

And it is Ethicon, not Ms. Wilson, who seeks to "create a false impression" when it argues that Ms. Wilson "applies the wrong standard" in her analysis of Ethicon's 2001 dFMEA. Def's Memo at 22-23. Indeed, Ethicon takes statements in Ms. Wilson's reports and deposition out of context and attempts to confuse the issues in this case. Ms. Wilson clearly explained in her reports which Ethicon procedures apply to Ethicon's dFMEA. Ex. A, Wilson TVT-R Report at 12-13. Moreover, Ethicon ignores controlling legal precedent by even raising this argument. As this Court has found, it "need not determine that the proffered expert testimony is irrefutable or certainly correct"—"[a]s with all other admissible evidence, expert testimony is subject to testing by 'vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" *Edwards*, 2014 U.S. Dist. LEXIS 92316, at *4; *see also Mathison*, 2015 U.S. Dist. LEXIS 59047, at *55 (noting that perceived oversights in an expert's analysis are proper fodder for cross examination and impeachment at trial)

F. Ms. Wilson is not offering medical opinions

Ethicon also mischaracterizes Ms. Wilson's reports by claiming they consist of medical opinions. Def's Memo at 24. In truth, not one of Ms. Wilson's opinions is a medical conclusion.

[1] One of Ethicon's expert witnesses in this case admitted at her deposition that having typos in her report "doesn't alter the quality of the opinions." Ex. E, Deposition of Elaine Duncan, 10/6/2015, at 62:2-6.

Instead, what Ethicon cites as "medical opinions" is factual background for Ms. Wilson's risk assessment opinions. *See* Ex. A, Wilson TVT-R Report at 24–31. Indeed, Ms. Wilson clearly explains this point in her reports: "The clinical implications of each of these complaint categories are discussed by medical physicians in other expert reports submitted in this litigation. I offer no opinions on the clinical implications or the frequency of any of those complications throughout the population in this report." *See* Ex. A, Wilson TVT-R Report at 24. Simply put, Ms. Wilson's opinions as to whether Ethicon's design controls and risk assessment complied with industry standards applicable to medical devices are well-qualified and reliable—and they are not "medical opinions."

G. Ms. Wilson's opinions regarding warning information in the risk management process are based on her experience

Product warnings that relate to risk assessment are relevant and within Ms. Wilson's expertise. *See* Ex. A, Wilson TVT-R Report at 11 (noting that "known or knowable risks will be identified, warned about, or mitigated" as part of the risk management process). Ethicon attacks Ms. Wilson's ability to offer any warnings testimony on the grounds that she is not a physician. Def's Memo at 25. However, Ethicon cites to no authority requiring that an expert be a physician, as opposed to a biomedical engineer like Ms. Wilson, to testify regarding risk assessment practices relating to warnings. Moreover, Ethicon failed to verify at Ms. Wilson's deposition whether her professional experience includes IFUs or product warnings. Ms. Wilson has clearly explained in her reports how warnings are a fundamental part of the risk management of a medical device. *See* Ex. A, Wilson TVT-R Report at 8 ("[w]arnings and training are the least effective means of minimizing risks of a product and should only be used as a last opinion"). As such, Ms. Wilson should be allowed to offer opinions regarding product warnings as a fundamental part of the risk management process in the medical device industry.

CONCLUSION

For the reasons stated herein, Plaintiffs respectfully request that the Court DENY Ethicon's Motion to Exclude the Testimony of Anne Wilson in its entirety.

This 9th Day of May, 2016 By: /s/ Edward A. Wallace

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CERTIFICATE OF SERVICE

I hereby certify that on May 9, 2016 I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive services in this MDL.

By: /s/ Edward A. Wallace